

**REMARKS**

Entry of this amendment is proper under 37 C.F.R. § 1.116 because the amendment places the application in condition for allowance for the reasons discussed herein, does not raise any new issue requiring further search and/or consideration, because the amendments amplify issues previously discussed throughout prosecution; and places the application in better form for an appeal should an appeal be necessary. Entry of the foregoing, reexamination, and further and favorable reconsideration of the subject application in light of the following remarks, pursuant to and consistent with 37 C.F.R. § 1.116 are respectfully requested.

As correctly stated in the Office Action, Claims 1-16 and 19-49 are pending in the present application. Claims 1-13, 19-32, 34, and 36-46 stand allowed. Claims 14-16, 33, 35, and 47-49 stand rejected.

By the present amendment, an Abstract has been provided on a separate page as requested by the Examiner. Claims 7, 14, 20, 21, 33, and 34 have been amended. Support for these amendments can be found, at least, in the claims as originally filed and in the specification on page 4, lines 6-16; page 5, lines 8-24; page 6, lines 7-10. New Claim 50 has been added. Support for this claim can be found, at least, on page 5, paragraphs 2-3 of the specification. No new matter has been added. Moreover, none of the amendments to claims were intended to limit the scope of any such claims or elements recited therein.

*Objection to the Specification*

The Office Action indicates that an abstract on a separate page is required. This objection is respectfully traversed. Applicants have previously provided an Abstract on a separate page with the Amendment filed October 22, 2003. Nevertheless, Applicants submit herewith an amended Abstract on a separate page as requested. Withdrawal of this objection is respectfully requested.

*Rejections Under 35 U.S.C. § 112, Second Paragraph*

Claims 14-16, 33, 35, and 47-49 stand rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite.

The Office Action indicates that Claims 14 and 15 lack antecedent basis for "a molten globule inducing reagent" because the claims from which it depends recite "a conversion agent." This rejection, to the extent that it may apply to the claims as amended, is respectfully traversed. Applicants respectfully submit that these are **two distinct moieties** and do not lack antecedent basis. The "conversion reagent" may be, e.g., oleic acid or the like, which stabilizes  $\alpha$ -lactalbumin into the biologically active form. The "molten globule inducing reagent" is, e.g., EDTA which forces the  $\alpha$ -lactalbumin into the molten globule-like state. This reagent appears for the first time in Claim 14 and is properly referred to as "**a** molten globule inducing reagent." Claim 14 has been amended to indicate the relationship of these two moieties.

The Office Action indicates that Claim 20 is indefinite as to how the calcium-binding sites are modified. Without conceding to the merits of this rejection, and solely in an effort to expedite prosecution, Claim 20 has been amended to indicates that the calcium-binding sites have been inactivated.

The Office Action indicates that Claim 21 is indefinite as unclear as to what the mutation is. Without conceding to the merits of this rejection, and solely in an effort to expedite prosecution, Claim 21 has been amended to recite that the cysteine residue is mutated to another amino acid.

The Office Action indicates that Claim 33 is indefinite as to what is considered a "low pH." Without conceding to the merits of this rejection, and solely in an effort to expedite prosecution, Claim 33 has been amended to recite a pH on the order of 2.

The Office Action indicates that Claim 48 is indefinite for lack of antecedent basis for "non-human product." This rejection is respectfully traversed. Applicants respectfully submit that this claim is consistent with Claim 1. Applicants have found that a co-factor or conversion reagent found in human milk, such as oleic acid, efficiently converts  $\alpha$ -lactalbumin to the biologically active form. However, now that this has been determined, it can be used to convert  $\alpha$ -lactalbumin from other sources including bovine  $\alpha$ -lactalbumin to biologically active material, as illustrated in the specification. Claim 1 does not require that the product is an entirely human product, merely that a component used, the conversion reagent, is one found in human milk. Accordingly, Applicants respectfully submit that current Claim 48 fully complies with 35 U.S.C. § 112, second paragraph.

Withdrawal of these rejections is respectfully requested.

### *Conclusions*

From the foregoing, further and favorable consideration of the subject application on the merits is respectfully requested and such action is earnestly solicited.

If there are any questions concerning this amendment, or the application in general, the Examiner is respectfully requested to telephone Applicant's undersigned representative so that prosecution may be expedited.

Respectfully submitted,

BURNS, DOANE, SWECKER & MATHIS, L.L.P.

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By:

  
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